CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Status of Changing Regulations - Guidelines Related to New Toxicity Values for TCE and PCE

William S. Bosan, PhD
Senior Toxicologist
Human and Ecological Risk Office
Cypress, CA

TCE Update

- IRIS (Integrated Risk Information System) released new toxicity criteria for TCE in Sept 2011.
  - The IRIS toxicity criteria are more health protective than OEHHA values.
- In April 2012, OEHHA updated the oral and inhalation No Significant Risk Levels (NSRLs) under Prop 65.
- OEHHA is currently revising its toxicity criteria as appropriate.

Toxic Endpoint	IRIS (9/2011)	OEHHA	Ratio of IRIS to OEHHA (Relative Conservativeness)
Carcinogenicity			
Inhalation Unit Risk (IUR) risk per µg/m^3	**4.1×10^{-6}** Kidney, Liver & non-Hodgkin lymphoma	**2.0×10^{-6}** (2004) Liver/Lung tumors	**2** **(2-fold more health protective)**
Oral Cancer Slope Factor (CSF) risk per mg/kg-day	**4.6×10^{-2}** Kidney, Liver & non-Hodgkin lymphoma	**5.9×10^{-3}** (2009) Liver/Lung Tumors	**7.8** **(8-fold more health protective)**
Chronic Toxicity (Noncarcinogenic effects)			
Inhalation Reference Concentration (RfC) µg/m^3	**2** Cardiac malformations, developmental immunotoxicity, adult immunological effects	**600** (REL) Occupational Exposure	**300-fold more health protective**
Oral Reference Dose (RfD) mg/kg-day	**5×10^{-4}** Cardiac malformations, adult immunological effects	**5×10^{-1}** (2009 PHG) Occupational Exposure	**1000-fold more health protective**

TCE Update Cont.

- Issues
  - How to interpret the IRIS non-cancer RfD and RfC for the industrial/commercial worker scenario - to protect sensitive group, adult women.
    - The RfC/RfD are based in part on increased fetal developmental effects (cardiac malformations) during the first trimester of pregnancy (a short exposure timeline).
  - What other States and Federal Agencies are doing to address the short term exposure to TCE

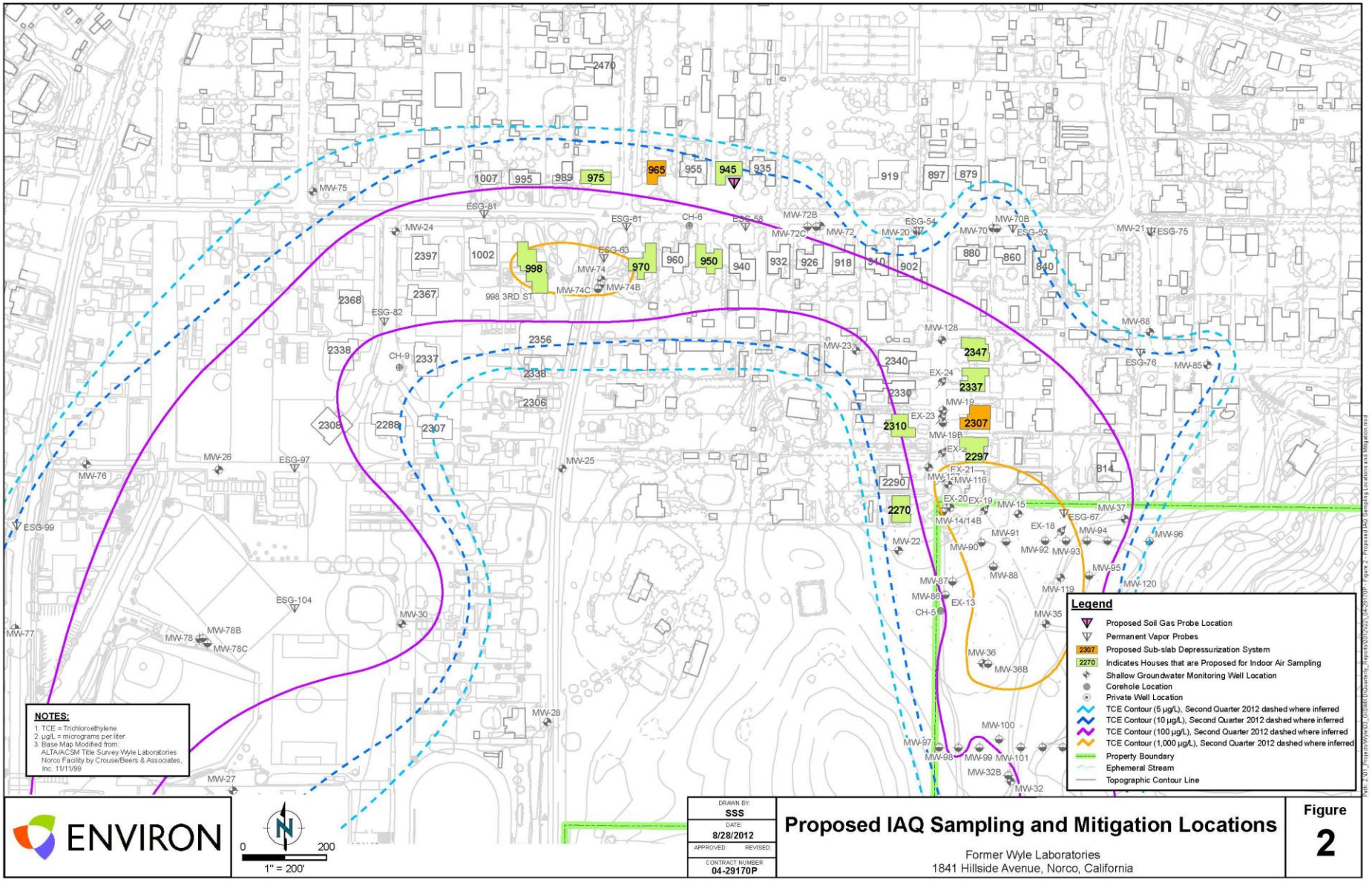
Regulatory Agency	Criterion	Residential ($\mu g/m^3$)	Industrial ($\mu g/m^3$)	Basis
MassDEP	Imminent Hazard (Interim Approach)	2 - 20	- - 	Fetal developmental effects Pregnant women/women of child-bearing age HQ = 1 Immune system effects All receptors - HQ = 10
NJDEP	Rapid Action Level	4	18	USEPA noncancer indoor air RSL for TCE, rounded up, and multiplied by a factor of 2
New Hampshire	Screening Level	2	8.8	If concentrations are detected at these levels, advise women of child bearing age and recommend relocation
USEPA Region IX	Proposed Remedial Action Level	-	15	USEPA RfC of 2 $\mu g/m^3$ adjusted to 5 $\mu g/m^3$ to account for a 10-hr work day, and then multiplied by a factor of 3 per EPA policy regarding short-term limits intended to account for uncertainty of non-carcinogenic risk values
USEPA Region X	Screening Level (short-term, noncancer)	2	8.4	Fetal cardiac malformations Not to be exceeded, average 21-day exposure
ATSDR	Minimum Risk Level (MRL)	2 (0.0004 ppm)	-	USEPA RfC selected as chronic duration MRL Chronic MRL considered protective of intermediate duration exposures

TCE Update Cont.

- Significance/Impact
  - Noncancer threshold (i.e., Hazard Index of 1) may exceed 1 at sites when the cancer risk is at the lower end of the risk management range or point of departure (1×10^{-6}).
  - Noncancer threshold may play more of a role in risk management decisions and must be discussed and considered.
  - When reviewing the risk assessment during the Five Year Review process, there is a potential that the original proposed remediation, land use controls, and/or institutional controls will have to be revised.

Wyle Laboratory, Case Study

- The Wyle Laboratories Site (site) is approximately 429-acres and located in Norco, California.
- Activities included the testing of aerospace components and systems using simulated physical and dynamic test environments.
- The primary chemical of concern is TCE.
- TCE has migrated off-site from the northwest boundary resulting in TCE contamination of shallow groundwater and soil gas beneath residences.

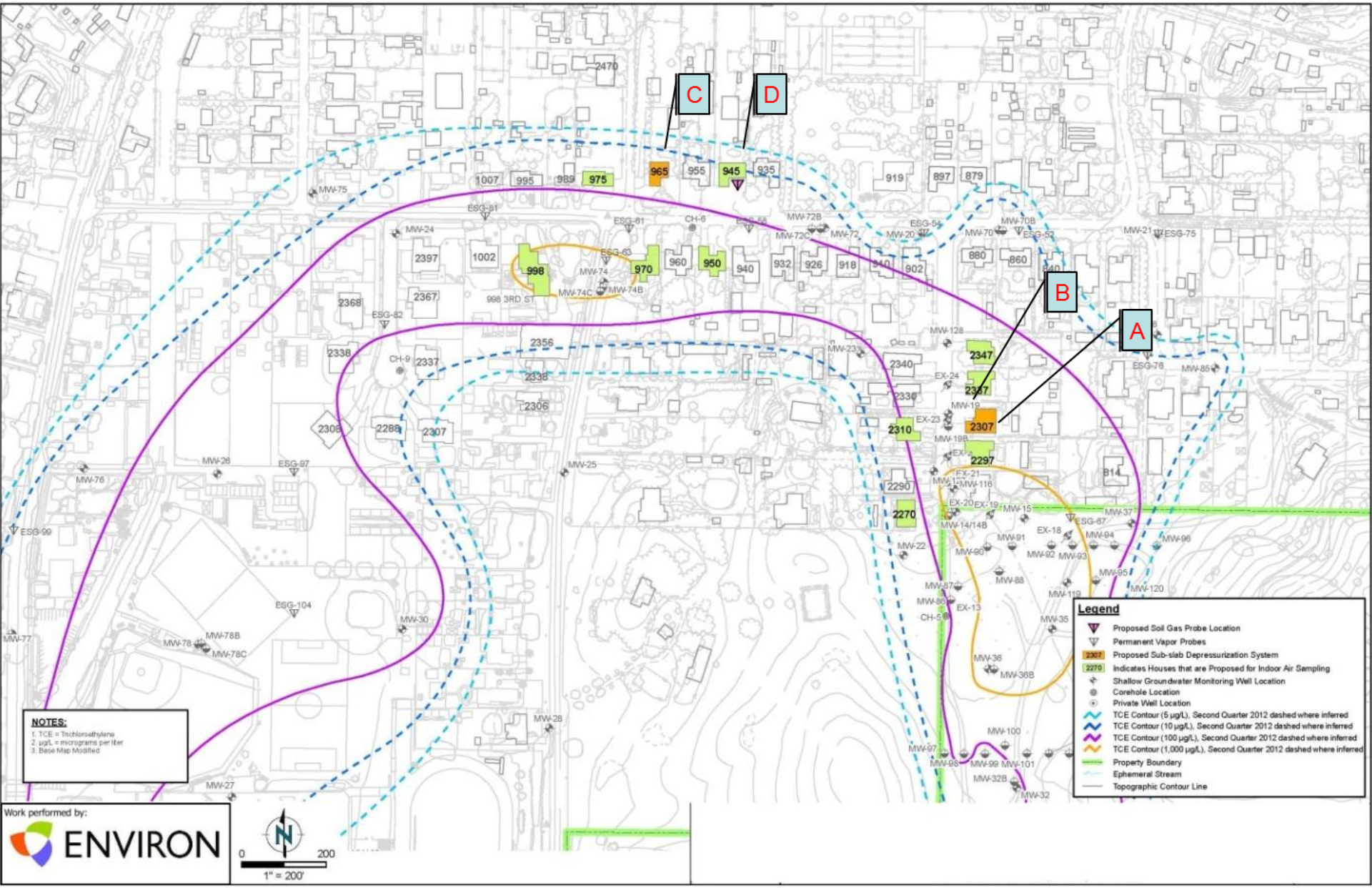

NOTES:
1. TCE = Trichloroethylene
2. ug/L = micrograms per liter
3. Base Map Modified from:
ALTA/ACSM Title Survey Wyle Laboratories
Norco Facility by Crouse/Beers & Associates,
Inc. 11/11/99
Legend
Proposed Soil Gas Probe Location
Permanent Vapor Probes
Proposed Sub-slab Depressurization System
Indicates Houses that are Proposed for Indoor Air Sampling
Shallow Groundwater Monitoring Well Location
Corehole Location
Private Well Location
TCE Contour (5 µg/L), Second Quarter 2012 dashed where inferred
TCE Contour (10 µg/L), Second Quarter 2012 dashed where inferred
TCE Contour (100 µg/L), Second Quarter 2012 dashed where inferred
TCE Contour (1,000 µg/L), Second Quarter 2012 dashed where inferred
Property Boundary
Ephemeral Stream
Topographic Contour Line
ENVIRON
0
200
1" = 200'
DRAWN BY: SSS
DATE: 8/28/2012
APPROVED:
REVISED:
CONTRACT NUMBER 04-29170P
Proposed IAQ Sampling and Mitigation Locations
Former Wyle Laboratories
1841 Hillside Avenue, Norco, California
Figure 2

Wyle Laboratory, Case Study

- 2006, DTSC sought access for IAQ sampling in 45 homes
- Access for 27 homes
- Conducted two rounds of IAQ sampling between 2006 and 2007
- 4 of 27 homes had elevated TCE
  - Between 1 and 4 $\mu g/m^3$

Wyle Laboratory, Case Study

- In 2007, 1E-06 indoor air level of 1.22 µg/m^3 TCE
- In 2011, EPA introduces new toxicity criteria for TCE
  - 1E-06 indoor air level for TCE now 0.43 µg/m^3
  - 1.0 HQ for TCE now 2 µg/m^3
- In 2012, Re-Sample indoor air in 4 homes
  - 3 of the 4 homes now require VIM


C
D
B
A
NOTES:
1. TCE = Trichloroethylene
2. µg/L = micrograms per liter
3. Base Map Modified
Legend
Proposed Soil Gas Probe Location
Permanent Vapor Probes
2307 Proposed Sub-slab Depressurization System
2279 Indicates Houses that are Proposed for Indoor Air Sampling
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Corehole Location
Private Well Location
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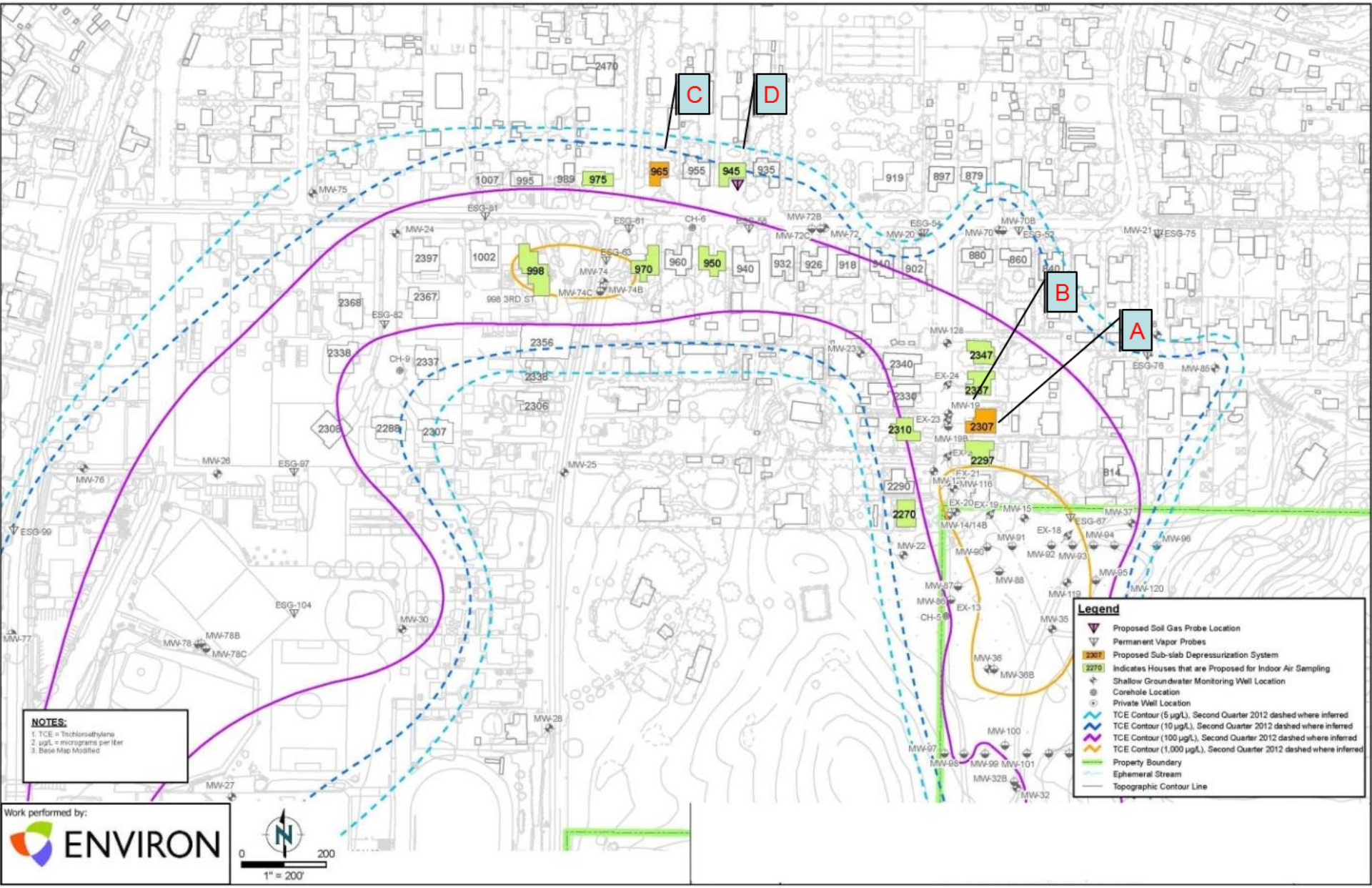
Property Boundary
Ephemeral Stream
Topographic Contour Line
Work performed by:
ENVIRON
N
0
200
1" = 200'

Home "A"		[TCE] ($\mu g/m^3$)
Bath	11/29/2006	**1.1**
	7/5/2007	**3.3**
	7/10/2012	**1.5**
	7/10/2012-dup	**1.5**
	7/10/2012-DTSC	**2.0**
Living Room	11/29/2006	**0.31**
	7/5/2007	**1.7**
	7/10/2012	**1.5**
	7/10/2012-DTSC	**1.9**
Out-door	11/29/2006	**<0.13**
	7/5/2007	**<0.13**
	7/10/2012	**<0.13**
	7/10/2012-DTSC	**0.19**
Recommended VI Mitigation		

Home "B"		[TCE] ($\mu g/m^3$)
Bath	11/29/2006	**2.6**
	7/9/2007	**0.39J**
	7/10/2012	**0.4**
	12/12/2012	**1.5**
Living Room	11/29/2006	**4.5**
	7/9/2007	**0.56**
	7/10/2012	**0.63**
	12/12/2012	**0.93**
Out-door	11/29/2006	**<0.13**
	7/9/2007	**<0.13**
	7/10/2012	**<0.13**
	12/12/2012	**0.20**
Continued Monitoring		

Home "C"		[TCE] ($\mu g/m^3$)	Home "D"		[TCE] ($\mu g/m^3$)
Bath	11/15/2006	4.3	Bath	11/29/2006	<0.13
	6/27/2007	1.5		7/5/2007	3.9
	7/9/2012	5.4		7/10/2012	0.58
	7/9/2012-dup	4.7		12/12/2012	2.0
	7/9/2012-DTSC	4.6		12/12/2012-dup	1.9
Living Room	11/15/2006	2.3	Living Room	11/29/2006	2.4
	11/15/2006-dup	2.5		11/29/2006-dup	3.2
	6/27/2007	0.95		7/5/2007	3.6
	7/9/2012	5.1		7/10/2012	0.72
	7/9/2012-DTSC	6.7		12/12/2012	1.8
Outdoor	11/15/2006	0.55	Outdoor	11/29/2006	<0.13
	6/27/2007	0.56		7/5/2007	<0.13
	7/9/2012	0.41		7/10/2012	<0.13
	7/9/2012-DTSC	0.45		12/12/2012	<0.13
VI Mitigation Installed			Recommend VI Mitigation		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PCE Update

- Health Effects of PCE
  - Noncarcinogenic effects
    - Neurotoxicity, kidney, liver, immune and hematologic systems, development and reproduction
  - Carcinogenicity
    - Liver Cancer
- Toxicity Criteria Sources
  - OEHHA toxicity criteria (2009)
  - USEPA/IRIS – Released new toxicity criteria in February 2012

Toxic Endpoint	IRIS (2/2012)	OEHHA	Ratio of IRIS to OEHHA (Relative Conservativeness)
Carcinogenicity			
Inhalation Unit Risk (IUR) risk per $\mu g/m^3$	**2.6×10^{-7}** Liver Cancer	**5.9×10^{-6}** (2009) Liver Cancer	**22** (22-fold less health protective)
Oral Cancer Slope Factor (CSF) risk per mg/kg-day	**2.1×10^{-3}** Liver Cancer	**5.4×10^{-1}** (2001) Liver Cancer	**250** (250-fold less health protective)
Chronic Toxicity (Noncarcinogenic effects)			
Inhalation Reference Concentration (RfC) $\mu g/m^3$	**40** Neurotoxicity - occupational exposure	**35** (2001) Neurotoxicity – occupational exposure	**Similar value**
Oral Reference Dose (RfD) mg/kg-day	**6×10^{-3}** Neurotoxicity - occupational exposure	**3.2×10^{-2}** (2001 PHG) Neurotoxicity	**5** (5-fold more health protective)

PCE Update Cont.

- Differences Between IRIS and OEHHA Cancer Toxicity Criteria
  - Both IRIS and OEHHA based their value on the same endpoint, incidences of liver cancer, in the same species, mouse.
    - However, the selected studies used different mouse strains
    - It is well documented in the scientific literature that strain/strain variation exists.

PCE Update Cont.

- HERO continues to recommend the OEHHA toxicity criteria.
  - Talk with the toxicologist assigned to your site for updates.
- It is HERO's understanding that OEHHA will not be re-reviewing its toxicity criteria or the IRIS document.
- OEHHA just reviewed the toxicity criteria in 2009.

Potential Impacts from Differences in Toxicity Criteria

	PCE		
	Soil Gas Screening Levels ($\mu g/m^3$)		
Scenario	OEHHA Toxicity Criteria (based at 10^{-6})	IRIS Toxicity Criteria (based at 10^{-6})	Fold Difference Between OEHHA and IRIS
Residential	180	4100	22x
Commercial /Industrial	1800	42000	23x
	Indoor Air Screening Levels ($\mu g/m^3$)		
Residential	0.41	9.4	22x
Commercial /Industrial	2.1	47	23x

Toxicity Criteria Updates

- Human Health Risk Assessment Note 3
  - DTSC Recommended Methodology for Use of U.S. EPA Regional Screening Levels (RSLs) in Human Health Risk Assessment Process at Hazardous Waste Sites and Permitted Facilities.

www. dtsc.ca.gov/assessingrisk/humanrisk2.cfm

DTSC Guidance Updates

- Revise inhalation dose equations consistent with EPA RAGS Part F
  - Unit Risk Factors, $(\mu g/m^3)^{-1}$
  - Reference Concentrations (mg/m^3)
  - Exposure time (hours/day)
- Guidance documents revised
  - PEA Manual
  - SEAM
  - DTSC J&E Model

SG-SCREEN
EPA Ver 2.0; 04/03

DRAFT--For HERO review only

DTSC
Vapor Intrusion Guidance
Final (October 2011)
(last modified 5/3/13)

Scenario: **Residential**

Reset to Defaults

Soil Gas Concentration Data

ENTER Chemical CAS No. (numbers only, no dashes)	ENTER Soil gas conc., C_g ($\mu g/m^3$)	OR	ENTER Soil gas conc., C_g (ppmv)	Chemical
79016	7.40E+02			Trichloroethylene

MORE ↓

ENTER Depth below grade to bottom of enclosed space floor, L_F (15 or 200 cm)	ENTER Soil gas sampling depth below grade, L_s (cm)	ENTER Average soil temperature, T_S (^oC)	ENTER Vadose zone SCS soil type (used to estimate soil vapor permeability)	OR	ENTER User-defined vadose zone soil vapor permeability, k_v (cm^2)
15	60	24			1.00E-08

MORE ↓

ENTER Vandose zone SCS soil type (Lookup Soil Parameters)	ENTER Vadose zone soil dry bulk density, ρb^A (g/cm^3)	ENTER Vadose zone soil total porosity, n^V (unitless)	ENTER Vadose zone soil water-filled porosity, θw^V (cm^3/cm^3)	ENTER Average vapor flow rate into bldg. (Leave blank to calculate) Q_{soil} (L/m)
	1.66	0.375	0.054	5

MORE ↓

NEW=> Lookup Receptor Parameters

NEW=> Residential

ENTER Averaging time for carcinogens, AT_C (yrs)	ENTER Averaging time for noncarcinogens, AT_{NC} (yrs)	ENTER Exposure duration, ED (yrs)	ENTER Exposure frequency, EF (days/yr)	ENTER Exposure Time ET (hrs/day)	ENTER Air Exchange Rate ACH $(hour)^{-1}$
70	30	30	350	24 (NEW)	0.5 (NEW)

END